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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,998	04/13/2001	Roberto A. Gaxiola	0399.2004-002	4319
21874	7590	11/03/2004	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,998

Applicant(s)

GAXIOLA ET AL.

Examiner

Cynthia Collins

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 and 74-97 is/are pending in the application.
- 4a) Of the above claim(s) 1-64, 74-81 and 86-97 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The Amendments filed June 21, 2004 and August 10, 2004 have been entered.

Claims 1-64 and 74-76 are withdrawn.

Claims 65-73 are cancelled.

Claims 77-97 are newly added.

Claims 1-64 and 74-97 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly submitted claims 78-81 and 86-97 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

In the response filed September 23, 2003, Applicant elected without traverse Group VIII, claims 65-73, drawn to a transgenic plant and a method of making a transgenic plant. Claims 65-78 were specifically directed to a transgenic plant which is tolerant to a salt comprising one or more plant cells transformed with exogenous nucleic acid (singular) which alters expression of a vacuolar pyrophosphatase, including AVP1 or a homologue thereof, and a Na⁺/H⁺ antiporter, including AtNHX1 or a homologue thereof, in the plant. Claims 68 and 69 required that AVP1 be present in the plant in a construct wherein AVP1 is operably linked to a double tandem enhancer of a 35S promoter. Accordingly the plants of the elected invention are transformed with an exogenous nucleic acid encoding the vacuolar pyrophosphatase AVP1.

Newly submitted claims 78-81 and 86-97 are directed to transgenic plants that comprise constructs different from the construct used to transform the transgenic plants of Group VIII. The transgenic plants of newly submitted claims 78-81 and 86-97 are transformed with constructs that comprise a chimeric Na⁺/H⁺ antiporter gene, including an AtNHX1 gene and including genes encoding the amino acid sequences of SEQ ID NOS: 1, 2 and 3 (corresponding to the AtNhxl Na⁺/H⁺ antiporter obtained from *Arabidopsis*, the HsNhe-6 Na⁺/H⁺ antiporter obtained from humans, and the ScNhxl Na⁺/H⁺ antiporter obtained from yeast). The transgenic plants of newly submitted claims 78-81 and 86-97 are distinct from the plants of the elected invention because they comprise exogenous nucleic acids encoding Na⁺/H⁺ antiporters that differ in structure, function and effect from the exogenous nucleic acid encoding the vacuolar pyrophosphatase AVP1 used to transform the transgenic plants of the elected invention. Accordingly examination of the transgenic plants of newly submitted claims 78-81 and 86-97 would require separate searches directed to plants transformed with each of the chimeric genes encoding each of the specific Na⁺/H⁺ antiporters recited in the claims.

Furthermore, while originally presented claim 70 required that the exogenous nucleic acid used to transform the transgenic plants of the elected invention alter the expression of a vacuolar a Na⁺/H⁺ antiporter (and a vacuolar pyrophosphatase) in the plants, none of the originally submitted claims, including those nonelected, required the transformation of a plant with an exogenous nucleic acid that encodes a Na⁺/H⁺ antiporter.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

Art Unit: 1638

prosecution on the merits. Accordingly, claims 78-81 and 86-97 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claim 77 is objected to because it is directed in part to a nonelected invention (a plant transformed with a chimeric Na⁺/H⁺ antiporter gene). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 83 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This a new matter rejection.

Claim 83 is drawn to the transgenic plant of claim 82 wherein the vacuolar pyrophosphatase gene is a plant or yeast gene. A yeast vacuolar pyrophosphatase gene does not find support in the specification as filed and thus constitutes new matter. Further, yeast vacuolar pyrophosphatase genes are not known in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 82-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Proc. Natl. Acad. Sci. USA, June 1994, Vol. 91, pages 6128-6132) in view of Carystinos et al. (Plant Physiol. , 1995, Vol. 108, pages 641-649) and Darley et al. (Plant Physiol. , 1995, Vol. 109, pages 659-665), and further in view of Applicant's admitted prior art.

The claims are drawn to a transgenic plant, progeny and seed having incorporated into its genome a chimeric vacuolar pyrophosphatase gene, including the plant vacuolar pyrophosphatase gene AVP1, operably linked to a 35S (CaMV) promoter double tandem enhancer that causes overexpression of said gene.

Kim et al. teach that heterologous expression of a chimeric *Arabidopsis* AVP1 vacuolar pyrophosphatase gene in yeast results in the production of a polypeptide that is a fully functional vacuolar pyrophosphatase enzyme (page 6130 Figure 1; page 6131 Figure 3 and Table 1; page 6132 Figure 4).

Kim et al. do not teach a chimeric gene in which a vacuolar pyrophosphatase coding sequence is operably linked to a 35S (CaMV) promoter double tandem enhancer, or overexpression of a chimeric vacuolar pyrophosphatase gene in a plant.

Carystinos et al. teach that vacuolar pyrophosphatase mRNA is increased in rice under anoxic conditions, and that vacuolar pyrophosphatase protein and vacuolar

Art Unit: 1638

pyrophosphatase enzyme specific activity are also increased in rice under anoxic or chilling conditions (page 643 Figure 1; page 644 Figure 2; page 645 Figure 4; page 646 Figures 5 and 6). Carystinos et al. also teach that vacuolar pyrophosphatase may be an important element in survival strategies of plants under hypoxic or chilling stress (page 649 column 2 second full paragraph).

Darley et al. teach that vacuolar pyrophosphatase protein level and enzyme activity are increased in mung bean under chilling conditions (page 662 Figures 2 and 3; page 663 Figure 4). Darley et al. also teach that vacuolar pyrophosphatase may be instrumental in protecting plants against chilling damage by sustaining energization of the vacuolar membrane (page 664 column 2 last paragraph).

The specification teaches at page 26 lines 20-22 that use of the double tandem enhancer of the 35S promoter of CaMV in plant transformation constructs for the expression of heterologous proteins was known in the art prior to Applicant's invention.

Given the teaching of Kim et al. that a chimeric *Arabidopsis* AVP1 vacuolar pyrophosphatase gene can be successfully expressed in yeast, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to express a chimeric *Arabidopsis* AVP1 vacuolar pyrophosphatase gene in a plant under the control of a plant specific promoter such as the double tandem enhancer of the 35S promoter of CaMV. One skilled in the art would have been motivated to do so in order to analyze the contribution made by elevated levels of vacuolar pyrophosphatase to plant tolerance of stresses such as chilling or anoxia, as suggested by Carystinos et al. and Darley et al. One skilled in the art would have had a reasonable expectation of success given the teaching of Kim et al. that the *Arabidopsis* AVP1 vacuolar pyrophosphatase gene encodes a

Art Unit: 1638

polypeptide that is a fully functional vacuolar pyrophosphatase enzyme, and given the teachings of Carystinos et al. and Darley et al. with regard to the increased production and activity of vacuolar pyrophosphatase in plants in response to chilling and anoxia.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Amy Nelson", with a long horizontal flourish extending to the right.

Cynthia Collins

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600